



Billing Code: 4120-01-U-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10151]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title of Information Collection: Data Collection for Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death; Use: CMS provides coverage for implantable cardioverter-defibrillators (ICDs) for secondary prevention of sudden cardiac death based on extensive evidence showing that use of ICDs among patients with a certain set of physiologic conditions are effective. Accordingly, CMS considers coverage for ICDs reasonable and necessary under Section 1862

(a) (1) (A) of the Social Security Act. However, evidence for use of ICDs for primary prevention of sudden cardiac death is less compelling for certain patients.

To encourage responsible and appropriate use of ICDs, CMS issued a “Decision Memo for Implantable Defibrillators” on January 27, 2005, indicating that ICDs will be covered for primary prevention of sudden cardiac death if the beneficiary is enrolled in either an FDA-approved category B IDE clinical trial (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual §310.1) or a qualifying prospective data collection system (either a practical clinical trial or prospective systematic data collection, which is sometimes referred to as a registry). Form Number: CMS-10151 (OMB#: 0938-0967); Frequency: Occasionally; Affected Public: Private Sector; Business or other for-profits, Not-for-profit institutions; Number of Respondents: 1,702; Total Annual Responses: 82; Total Annual Hours: 139,356. (For policy questions regarding this collection contact JoAnna Baldwin at 410-786-7205. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS’ Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by **IOFR—insert date 60 days after date of publication in the Federal Register**:

1. Electronically. You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

Dated: April 17, 2013

Martique Jones,

Deputy Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

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